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Appn. Title: Therapeutic Uses of Pungent Botanicals and Their Related Compounds

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Information Disclosure Statement

Commissioner of Patents and Trademarks Washington, District of Columbia 20231

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Sir:

Attached is a completed Form PTO-1449. Copies of the pertinent parts of the newly cited Tierra, and Lust references are enclosed thereon. Copies of the other cited references are of record in the IDS of the prior case #08/376,045 filed 1995 January 20 with the exception of the Duke, Purseglove, and Chemical Abstracts references which are of record in the IDS of prior case #07/886,640 filed 1992 May 21. Following are comments on any non-English-language references pursuant to Rule 98:

The exact date of the Levy references are not known at this time, and may have come after Applicant date of priority.

1. Levy recommends a lotion for treatment of Woody Tongue, a deep tissue fungal disease in cattle. The lotion contains a minor portion of paprika (Capsicum annum) in a proportion of sixty four to 1 (64:1) against equal parts of seaweed brew and vinegar. The lotion is administered by massage as one part of a five-fold regiment of combination internal and external therapies (fasting, dieting, tonification ect.). At least five additional herbs of various proportions and administrations are further recommended as part of the total treatment.

Conversely, the current invention requires a minimal number of common administrations of a singular ingredient (pepper) within a simple carrier. This is far less complicated, and apparently much more effective than this prior art treatment.

- 2. Levy recommends lemon juice, and some six other separate herbs as the preferred treatment for fungal infections of the skin; none of which are pepper, or *Zingiberaceae* species as in the claims.
- 3. Levy recommends red pepper as an "internal disinfectant," protecting against impure food, harmful bacteria in milk, and treatment for worms. These are not fungal diseases, *Piperaceae*, or *Zingiberaceae* genera, or pathogens as found in the claims.
- 4. Kloss indicates red pepper tea as an antiseptic gargle for septic sore throat and diphtheria. These diseases are bacterial, not fungal in origin. The claims directed toward bacterial uses do not encompass topical treatment of sore throat with red pepper. While viruses can cause sore throat, the claim recites genera of the family *Zingiberaceae* which are relatives of ginger, and not actual peppers.
- 5. Kloss recommends drug store ointments, or any of six different herbs to treat ringworm, none of which is a pepper species as in the claims.
- 6. Duke and Purseglove state that sweet peppers (Capsicum annum) contain solanine.
- 7. Fontaine et al, state that solanine has antifungal properties similar to tomatine. Tomatine had been shown to be inhibitory to certain dermatophytes, and deep tissue pathogens in vitro. The source of the solanine, however, was apparently potato, and not pepper, which has a significantly lower level.
- 8. Quisumbing cites Burnett's description of a scabies treatment of pepper (*Piper*) leaves boiled in oil and applied externally. This would not produce the same compounds as a common cold solvent extract, or hydrolysis of the same within the carriers mentioned.
- 9. Burnett also states that juice from pepper (*Piper*) leaves in an ointment mixed with lard is used in the treatment of tinea capitis. The current invention neither requires, nor recommends lard. It is indeed probable that lard diminishes the effectiveness of this medication.
- 10. In the opinion of Levy, lard lent protection, rather than harm to certain skin pathogens, and never allowed it in her own skin preparations.
- 11. Chemical Abstracts 97(11): 92598e, 103(25):210886q, 112(19):175337y, and 116(3):18385c, of record (not included) cited earlier by examiner search mention testing of Piper plant extracts against plant, not human or animal pathogens. Neither do the references, however make no mention of subjecting the extracts to the further step of hydrolysis as in the claims.

Newly cited references:

- 12. Tierra states that the root of kava kava (*Piper methysticum*) is used in an antiseptic douche for vaginitis. The claims avoid this reference by reciting other species hitherto unsuggested by the prior art.
- 13. Lust states that oil from the unripe fruit of cubeb (*Piper cubeba*) is used in an antiseptic against gonorrhea. The claims avoid this reference by reciting other species hitherto unsuggested by the prior art.

Respectfully

Jeff J. Staggs, Applicant

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Date: 1997, /0/10

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